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[1]The Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States (Off. Rec. Wld Hlth Org., 2, 100), and entered into force on 7 April 1948. Amendments adopted by the Twenty-sixth, Twenty-ninth, Thirty-ninth and Fifty-first World Health Assemblies (resolutions WHA26.37, WHA29.38, WHA39.6 and WHA51.23) came into force on 3 February 1977, 20 January 1984, 11 July 1994 and 15 September 2005 respectively.

Background

The World Health Organization (WHO) is mandated by its constitution[1] (1) to support and promote health research The World Health Report: research for universal health coverage (2013) (2) emphasized WHO's role in advancing research that addresses the dominant health needs of its Member States, supporting national health research systems, setting norms and standards for the proper conduct of research and accelerating translation of research findings into health policy and practice in order to accelerate progress towards universal health coverage (UHC).

In addition, in the WHO Regional Office for the Eastern Mediterranean (WHO/EMRO), the strategic document, Shaping the future of health in the WHO Eastern Mediterranean Region: reinforcing the role of WHO (2012) (3), outlined the following five strategic health priorities for the Region: health system strengthening; emergency preparedness and response; maternal, reproductive and child health and nutrition; noncommunicable diseases, in addition to the unfinished agenda of communicable diseases. A key element within all the priority areas is

building national capacities in research for health (4).

To help realize WHO's role in health research and target the Eastern Mediterranean Region's priorities, under the department of Information, Evidence & Research, the WHO/EMRO has the Research, Development & Innovation group and a Research Policy & Development unit, which (among other functions) serves as the Secretariat of the Eastern Mediterranean Research Ethics Review Committee. Moreover, the unit coordinates three types of health research grants, namely Research in Priority Areas of Public Health grants which addresses the five strategic health priorities of the Region; the Improved Programme Implementation through Embedded Research grants offered in collaboration with the Alliance for Health Policy & Systems Research (WHO/HQ), and the Tropical Disease Research – Small Grants Scheme, offered in collaboration with the WHO/UNDP/World Bank Special Programme for Research and Training in Tropical Diseases (WHO/HQ). In this respect, it is worth referring to the current cooperation of WHO/EMRO with different stakeholders, including UN agencies such as UNESCO's Regional Office in Cairo, in the field of bioethics applications with special emphasis on ethical conduct of health research.

A recent WHO/EMRO survey for situation analysis of bioethics in the Region (Bioethics in the EMR: a situation analysis, unpublished report, 2015) showed that most Member States have either national bioethics committees or institutional review boards, which safeguard ethical conduct of health research and protect the dignity, human rights, and well-being of its human participants. However, they still need technical support to develop the capacities needed to maintain such bodies. In addition, a recent review of research published in our flagship Journal, the Eastern Mediterranean Health Journal (EMHJ), for the period 1995–2014 (5), showed almost equal distribution of health research published on all the regional strategic health priorities, except emergency preparedness and response. With the Region suffering from crises/emergencies in more than half of its Member States, this is an area which urgently needs evidence generated from sound health research.

Eastern Mediterranean Research Ethics Review Committee

In order to ensure scientific rigour and ethical conduct of health research recommended for funding under the above-mentioned grants, the Regional Director re-formulated the Eastern Mediterranean Research Ethics Review Committee to include external (from Egypt, Islamic Republic of Iran, Lebanon, Morocco, Tunisia, UNESCO) as well as in-house members with an essential function to "review the protocols of all health research projects involving human subjects submitted to WHO for funding in the Region". Such review aims to protect the dignity, integrity, human rights, safety and well-being of all the people participating in such research. The Committee also has the authority to verify that ongoing studies comply with the Organization's policies and regulations for conduct of health research in the Region.

During the review process of the health research protocols, the Committee is expected to ensure compliance with the International Ethical Guidelines for Biomedical Research Involving Human Subjects (6), as well as other international guidelines which govern ethical conduct of health research (7–10), including equitable selection of subjects, appropriate safeguards to protect the rights and welfare of research participants, especially vulnerable groups, full informed consent process and protection/maintenance of privacy of individuals and confidentiality of the data collected. Methodologically, the review should ensure that the health research topic will add to scientific knowledge and is relevant to institutional and community interests, and that the research design is appropriate and study instruments are acceptable. For interventional studies, the review has to safeguard that clinical research facilities at the study site are appropriate, that all researchers involved have appropriate qualifications, training and experience, and that potential benefits to be gained from the research outweigh any expected risks. Moreover, operational health research must provide evidence which supports sound health policy and decision-making in the Region (knowledge translation).

First meeting of the re-formed Committee

In light if the re-formulation of the Eastern Mediterranean Research Ethics Review Committee the Regional Office recently convened a meeting of the Committee during the period 6–7 September, 2015. The objectives of the meeting were to: review the Committee's work in light its updated functions; ensure compatibility of the Committee's work with international guidelines for review of health research on human subjects; update the current review process for health research supported by WHO; and address new health research challenges in the Eastern Mediterranean Region, including health policy and systems research. Following the 2-day deliberations, the meeting provided a set of recommendations for ensuring compatibility of the Committee's work with international guidelines for health research (7–10), updating the ethical review process (with special focus on its checklists) and providing special advice for current challenges in health policy and systems research.

Recommendations

The Committee made the following recommendations: encourage/solicit research on public health priorities in the Region, especially on crises and emergencies; develop/enforce national laws and regulations which govern bioethics and related research; emphasize vigilance by editors of scientific journals to avoid fraud and falsification of health research submitted for consideration for publication; develop/support/accredit national bioethics committees which could oversee the work of institutional committees, including institutional review boards; establish different ethical review committees according to need (e.g. for research on human subjects; on animals, etc.); promote rigorous ethical review process on different levels (institutional/national/regional); use the expertise of the global WHO-Collaborating Centres on bioethics and regional technical collaborating centres; establish a regional collaborating centre

on bioethics; support capacity-building activities in bioethics/ethical conduct of health research; supporting institutional clearance (in the absence of national clearance); establish national registries for clinical trials and research; regulate pharmaceutical companies/clinical studies.

The Committee also advised that proposals on health policy and systems research should be reviewed using an expeditious process/applicable questions in checklists. In addition, it recommended that some members of review committees (especially at a national/institutional level) should have training in health policy and systems research and that different stakeholders should be involved with the review process (as applicable).

The Committee carefully reviewed the currently used checklists for review of submitted research proposals recommended for WHO funding. It recommended modification/addition of some questions and added a section on conflict of interest as well as special sections for “informed consent process for vulnerable groups”, including minors, pregnant women, emergencies, and mentally challenged people. These are to be drafted in the near future.

In the closing session, the Regional Director strongly supported the role and functions of the Committee in evaluating the ethical conduct of WHO-funded health research carried out in the Region and emphasized the importance of collaboration with UN organizations working in the field of bioethics, especially UNESCO (with special focus on supporting national bioethics committees and inclusion of bioethics in curricula of health sciences’ colleges).

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